FDA Office of Generic Drugs
Keynote Address

Creating The Path to Success with GDUFA

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Disclaimer

- This presentation reflects the views of the speaker and do not reflect official FDA, HHS, or other government opinion or policy.

- I have nothing to disclose.

OUTLINE

- Preparing for Year 3 of GDUFA & goal dates
- What you are seeing with Year 3 submissions
- What you should expect to see with pre-Year 3 submissions

THANK YOU

- Your patience, feedback, & input during GDUFA implementation is greatly appreciated
- Many changes, challenges, alignment, etc. necessary to implement this historic program
- We recognize that this has been difficult, disruptive, and painful
- **GOAL** - New, sustainable initiatives designed to meet all GDUFA commitments (and more) with fairness across all applications, applicants
- **OUTCOME** – Affordable, quality medicines for the American public

Generic Program State

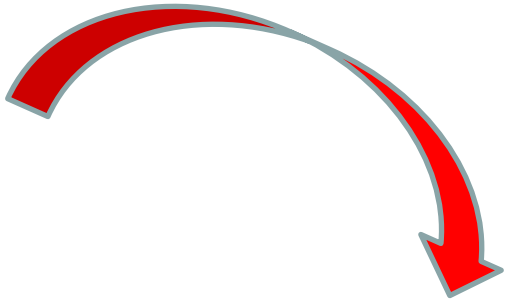
PAST

- Increasing number of ANDAs
- Tremendous backlog
- Disjointed reviews
- Fragmented discipline deficiencies

PRESENT

- Revved up for GDUFA Goal Dates
- Issuing Complete Response Letters
- Aligning functions
- Dunner Letters
- Target Action Dates (TAD)
- Real Time Communication (RTC)

Generic Program State



GDUFA Years 3, 4 & 5

Robust, formal Program with Significant Support
Predictable
Timely
Less review cycles
High Quality Reviews
High Performing
Highly Functional
Makes all Commitments
Highly Respected

MOVE THE FREIGHT…

Pre-Year 3 work:
Controls (~470)
ANDAs (~3,300)
PASs (~500)
Inspections
CBE 0/30 (~3,500)

PLUS non-goal date work:
CBE 0/30
Guidance requests
Pre-ANDA mtg requests

Data from Platform, 2/2/15

…while meeting GDUFA goal dates

<u>Year 3 GOAL date work</u>:
Controls
ANDAs
PASs
Post CR meetings

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Riding the Waves of GDUFA

OGD is an agile environment….
creating new processes, tools and training to enable quicker response times

GDUFA Years 1 & 2 – BUILD THE PROGRAM

Deep, foundational restructuring to fulfill GDUFA commitments

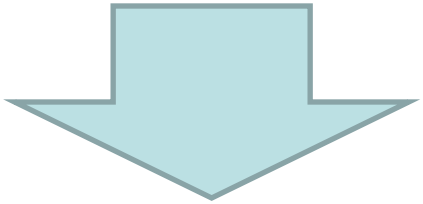
"Riding the Waves"

- Implementing a new program (GDUFA)
- Moved to White Oak
- Reorganized and became a Super Office
- New staffing infrastructure
- New IT platform
- New OPQ

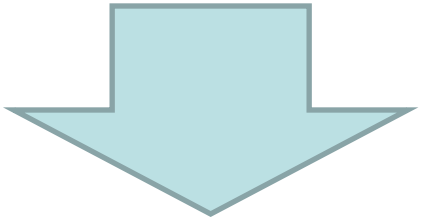
"Riding the Waves"

- More than expected submissions
  - Year 1 (FY13) = 968
  - Year 2 (FY14) = 1473
- Getting ready for incoming submissions with goal dates for the first time

GDUFA



TRANSFORM THE PROGRAM
and
PERFORM WHILE TRANSFORM



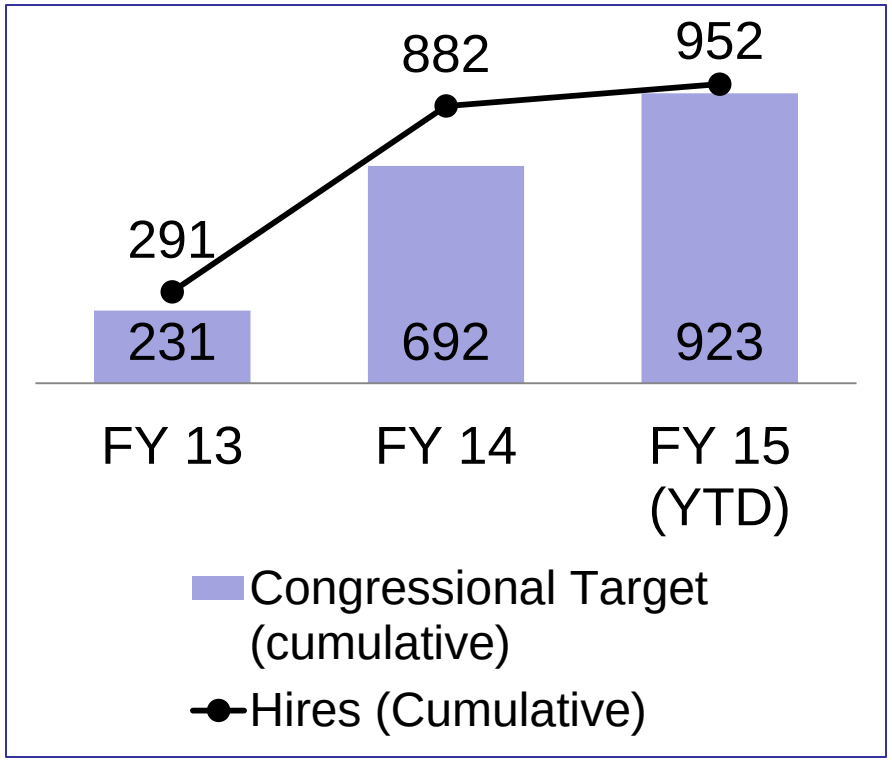
ENHANCING OUR QUALITY SYSTEM

SUCCESSFULLY IMPLEMENTING GDUFA …QUALITY SYSTEM

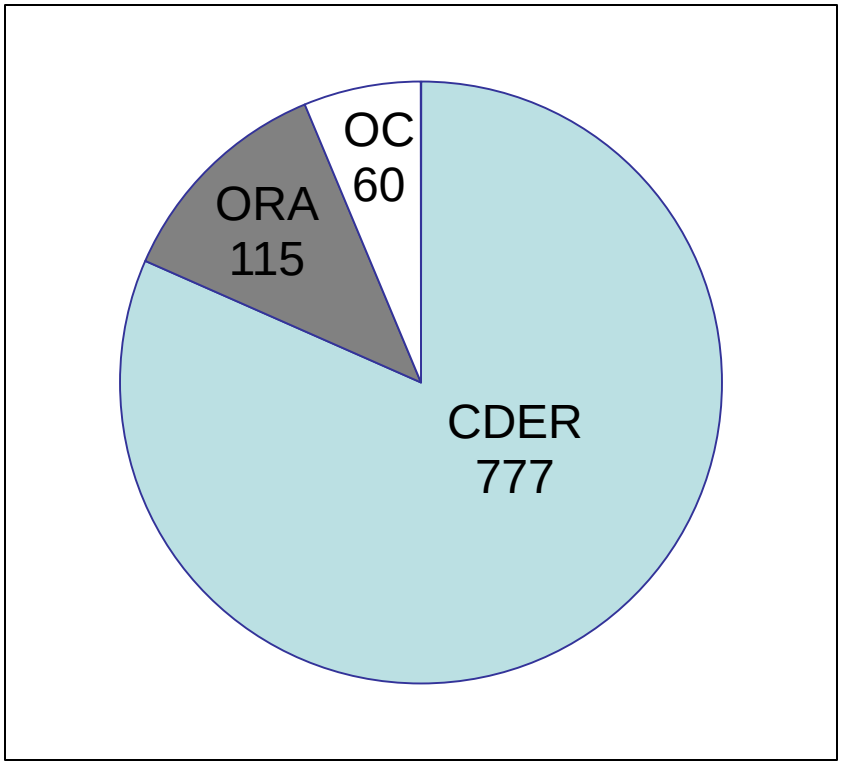
- Hire & Train
- Process & Policy
- Inspectorate
- Informatics (“Platform”)
- Regulatory Excellence
- Agency Alignment

GDUFA Hiring: GDUFA Goal Met

Hiring Progress by Fiscal Year



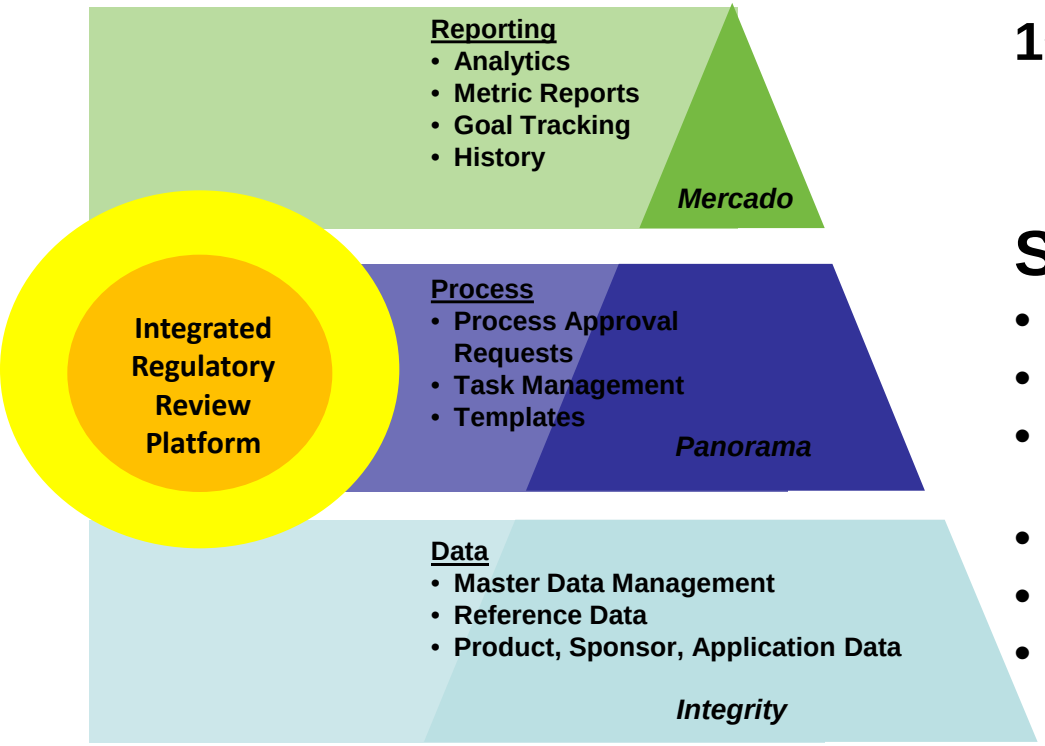
Hiring by Center/Office



All data through Nov. 19, 2014

EFFICIENCY ENHANCEMENTS

Enhanced IT Systems & Technology



1st major release October 2014

SUPPORT OF:

- Original ANDA
- Supplemental ANDA
- Controlled Correspondence (related to generic drug development)
- Facility Inspection Management
- User fee checks
- Legacy data/applications

REGULATORY EXCELLENCE

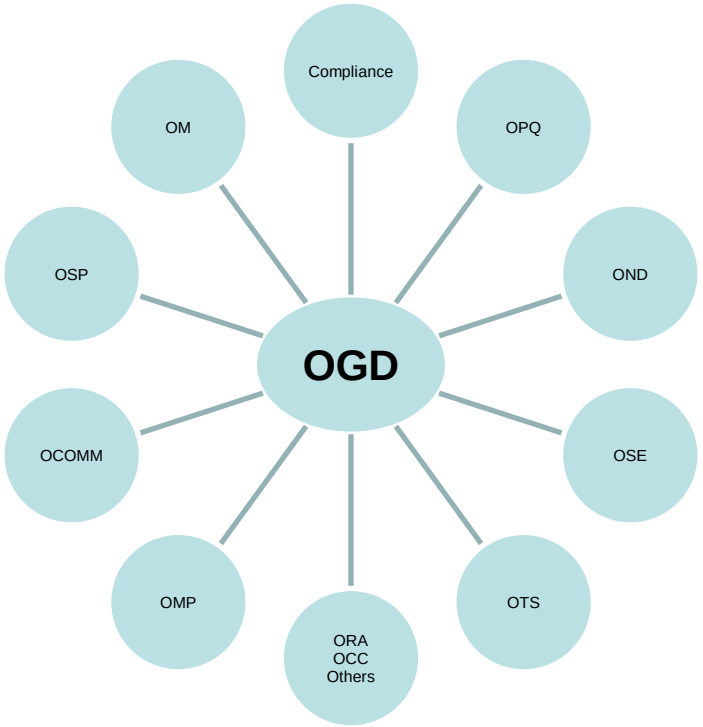
- Build OGD Office of Policy
- Providing clarity on Agency expectations, esp. per GDUFA
- Industry should expect to see **MORE**…..

- **GDUFA Specific Guidances:**
  - Refuse to Receive (RTR)
  - Format and Content of ANDA submissions*
  - Amendments & ECDs (Tier submissions)*
  - Prior Approval Supplements*
  - Controlled Correspondence*
- **GDUFA Specific MAPPs:**
  - ANDA Prioritization Policy*
  - Prioritization Governance*
  - Communication with Industry* (under revision)

* These guidances and MaPPs are not required under GDUFA

AGENCY ALIGNMENT

- GDUFA Review Implementation Team
- Generic Drug Review Platform
- GDUFA Steering Committee
- CDER Lifecycle Management Board
- GDUFA Command Center
- FDA Program Alignment Group (PAG)



OUTLINE

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- **What you are seeing with Year 3 submissions**
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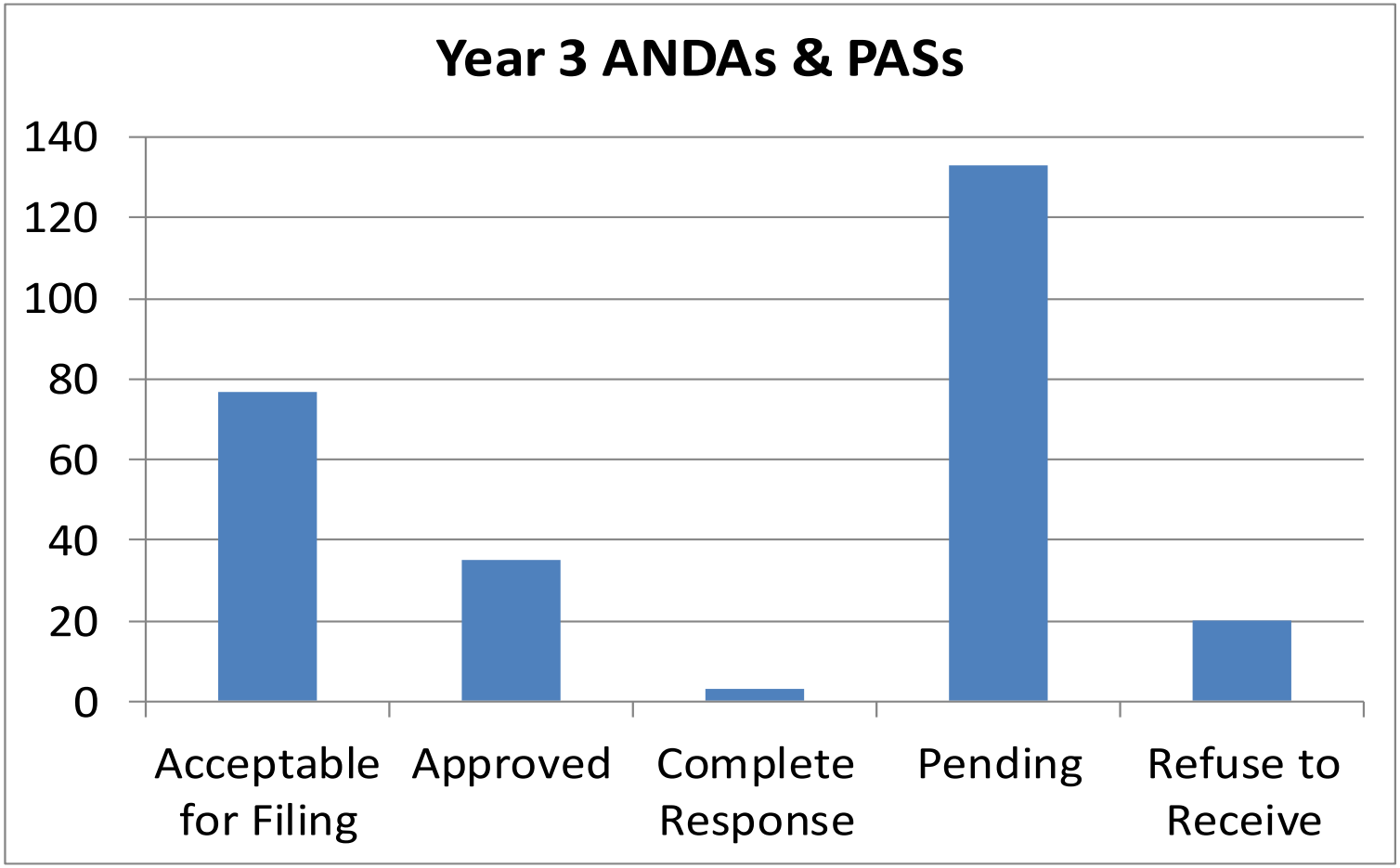
CURRENT STATE for GDUFA Year 3 Submissions ….Seeing Benefits of GDUFA

- FY2015 submissions & communications
  - Responses to controls
    - **217**
  - "Accepted for filing" notifications
    - **77** (average time <30 days)
  - PASs – approved (ahead of GDUFA goal date)
    - **35**
  - Scientific review disciplines picking up Year 3 ANDAs, real time communications will occur

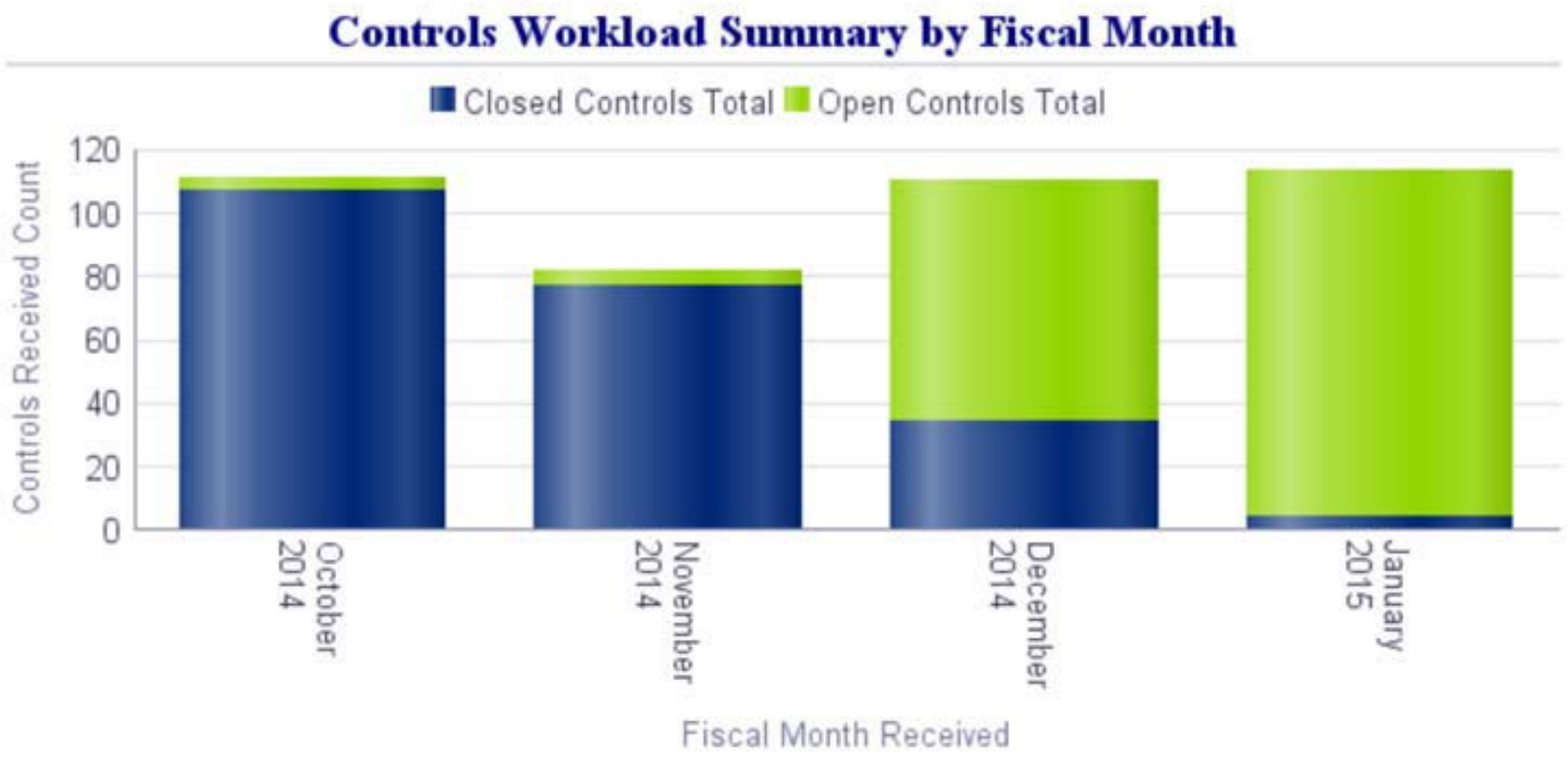
Data from Platform, 2/2/15



(Data from Platform, 10/1/14-2/2/15)

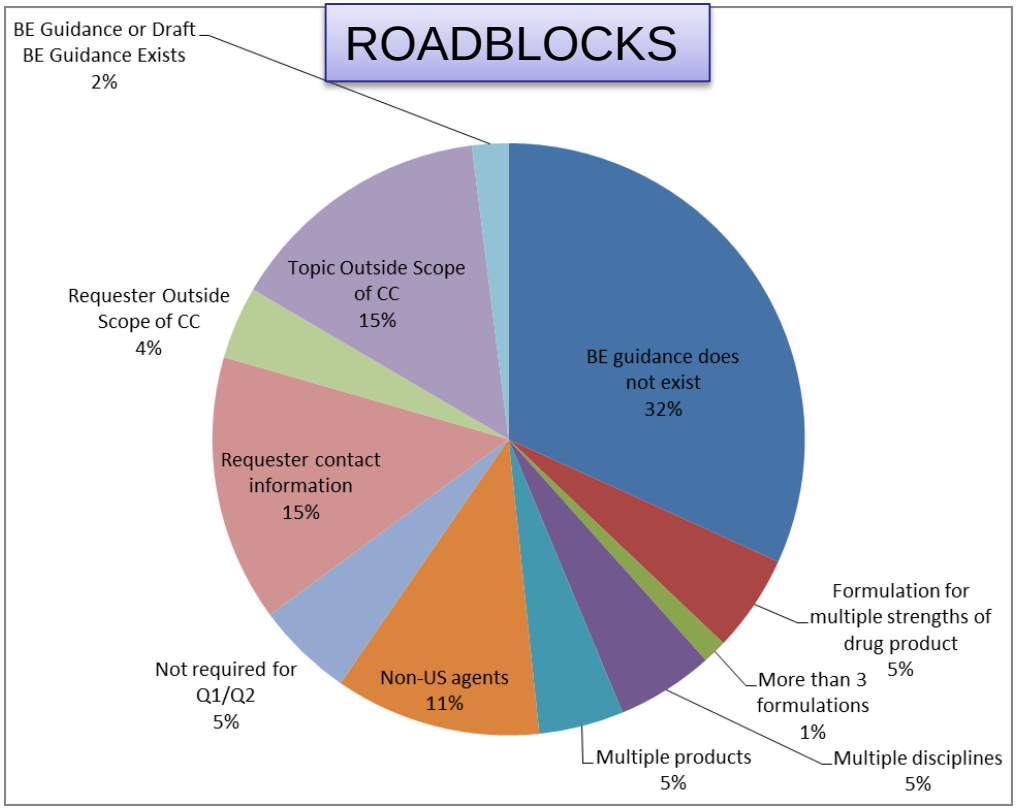
YEAR 3 “Controls”

(Data from Platform, 10/1/14-2/3/15)



CONTROLS in YEAR 3

Controls received through 1/15/15



Roadblocks to Expedient Response
Formulation for multiple strengths
More than 3 formulations
Multiple disciplines
Multiple products
Non-US agents
Not required for Q1/Q2
Requester contact info
Requester outside of scope
Topic outside of scope
BE guidance exists

SEE DRAFT GUIDANCE ON CONTROLS WRT GDUFA-
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM411478.pdf

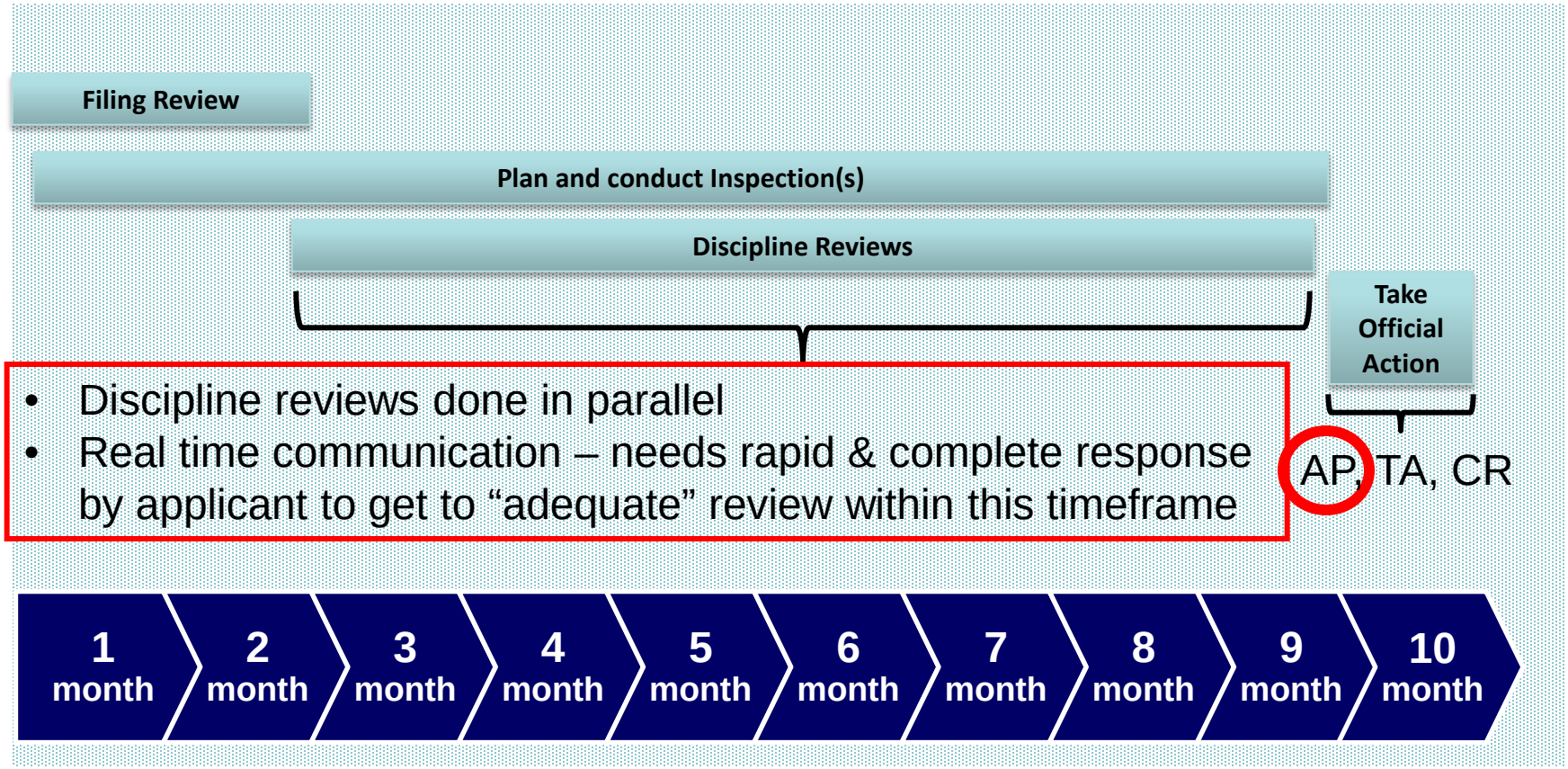
Top reasons for RTR in Year 3

- Fees (inadequate, improper)

- Inadequate Stability
- Inadequate Dissolution
- Inadequate BE studies or failed studies only

- Inadequate response
  - MISSED timeframe - No response to minor deficiency communication within prescribed time frame
  - Incomplete deficiency response

UNDER GDUFA….
ANDA review process*



*for Year 4 or 5 original ANDA

YEAR 3 original ANDAs

Industry should expect to see MORE:

1. More communication on ANDAs
   - "Information requests" (IRs)
   - More requests (RTC, IR, ECDs, etc.) with strict timeframes & need for quick and complete responses to the Agency
     - During Filing Review
     - During Discipline Reviews
   - More communication with RPMs
2. Probably more RTRs

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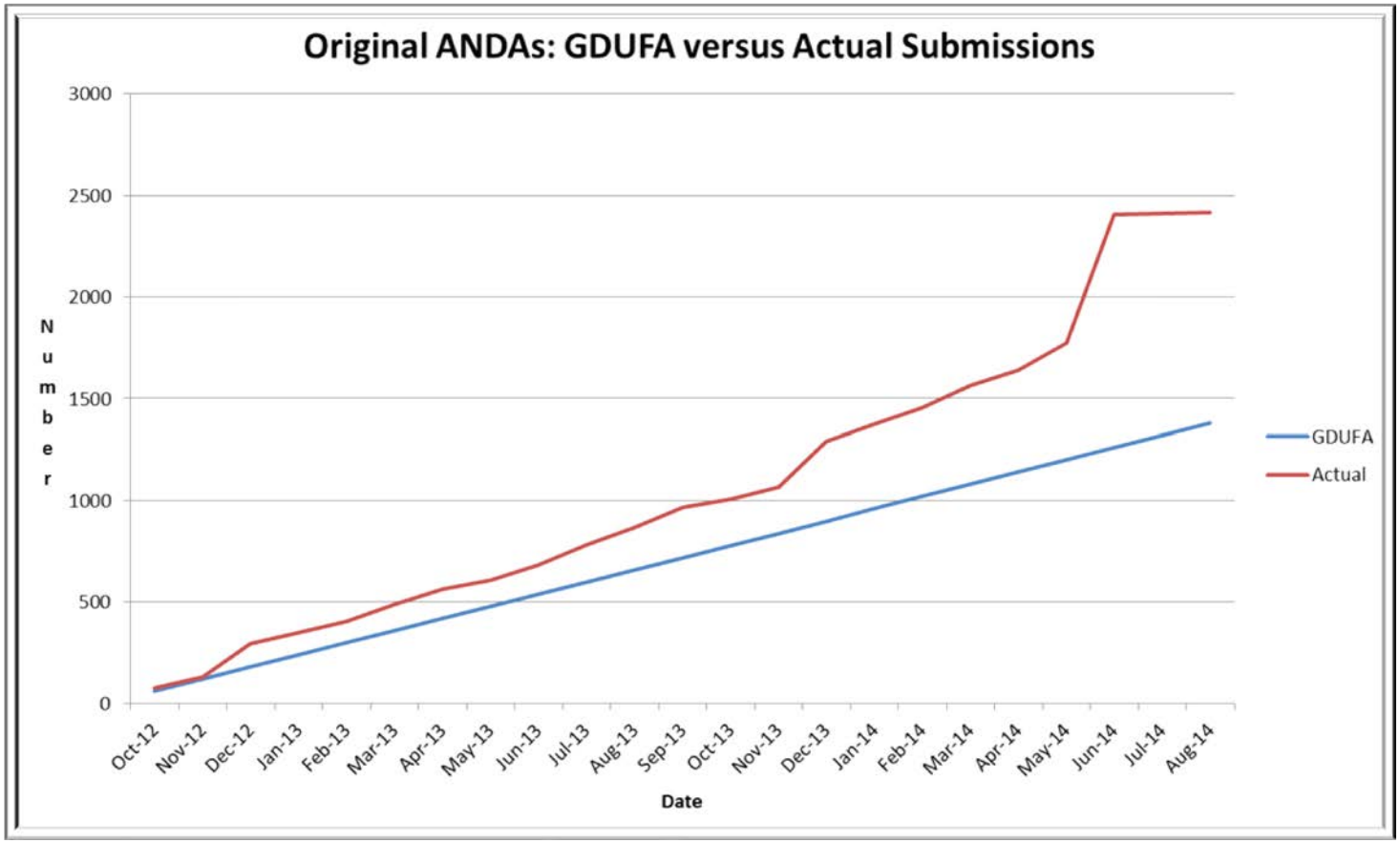
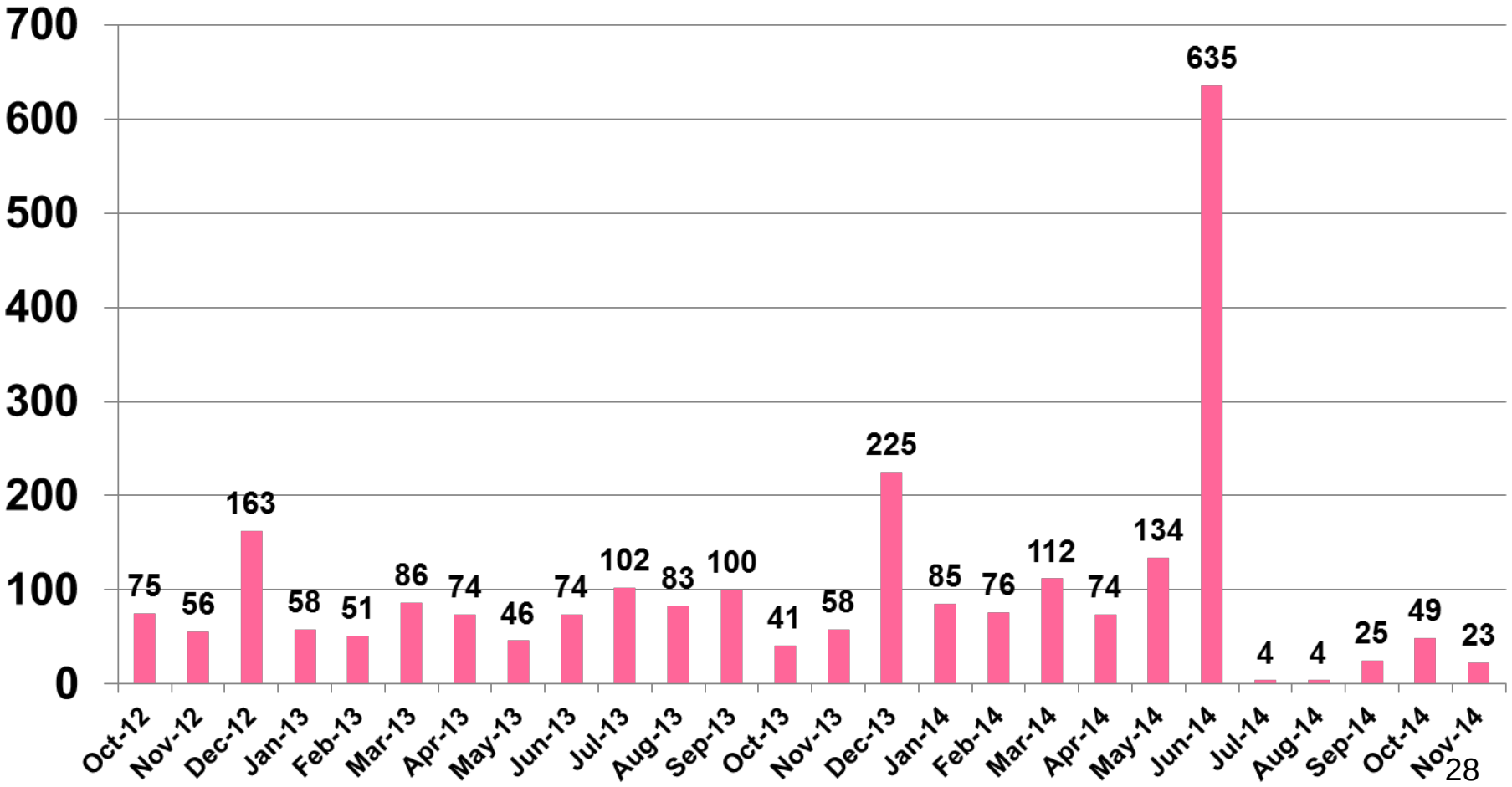
More ANDAs submitted than GDUFA Predicted



Prepared by Glen Smith (OPQ)

ANDA Receipts



PRE-YEAR 3 WORKLOAD

- GDUFA Backlog
  - 2866 original ANDAs
- Year 1 and Year 2 ANDA submissions
  - Year 1 (FY13) = 968
  - Year 2 (FY14) = 1473
- With FDA = ~3,300
- With Industry = ~700
- **TOTAL = ~4,000 ANDAs "pending"**

FDASIA requires reporting time pending with both FDA & industry

GDUFA BACKLOG

- 2866 original ANDAs
- 1873 PAS supplements

GOAL: 90% get first ACTION by end of GDUFA YR 5 (9/30/2017)

First Actions 10/1/2012 to 9/26/2014:

	Original	PAS	Total
Number with First Action**	1707	1362	3069
% Complete	60%	73%	**65%**
AP	447	779	1226
TA	105	3	108
CR with inspection	953	408	1361
RTR	70	2	72
WD	132	170	302

** Numbers are based on current data and will be further scrubbed for formal reporting purposes.

APPROVALS & ACTIONS

	PRE-GDUFA FY2012	GDUFA FY2013	GDUFA FY2014*
ANDA approvals	517	440	409
PAS approvals	275	535	659
Tentative Approval (TA)	102	95	91
Complete Response (CR) (w/ and w/o inspection)	84	1251	1254
TOTAL ACTIONS **	978	2226	2413
TOTAL APPROVALS (minus CR)**	894	1070	1159
DMF Completeness Assessment (CA)	0	1699	1775

* Numbers are based on current data and will be further scrubbed for formal reporting purposes

** FDA will aspire to the extent possible to maintain levels of productivity at least similar to pre-GDUFA levels, while hiring and training incremental staff necessary to achieve the program performance goals, building necessary systems and implementing outlined program changes in years 1 and 2 of the program (GDUFA Commitment Letter, page 3)

PRE-YEAR 3 WORKLOAD

- Improve not only communications, but also performance
- Goals:
  - "Move the freight"
  - Focus on approvals, not just actions
  - Need to get applications to an approvable state
  - Don't let big first generics slip through the cracks
- Do all this while meeting GDUFA goals on all Year 3 applications

TARGET ACTION DATES (TADs)
The Holistic View

- TAD is an internal FDA deadline for **action** on an Application
  - ANDAs only
    - Not for pending PASs or controls
    - Not amendments; Not discipline specific reviews
  - Action = AP, TA, or CR
- TAD is not a GDUFA goal date
- TADs are not required by GDUFA
  - Not a reported metric

PRE-YEAR 3 WORKLOAD
Assigning Target Action Dates (TAD)
"A Work in Progress"

- Assign Target Action Dates (TADs) to all pre-Year 3 applications (Not all at once, and with caveats)
  - To manage inventory and synchronize review work
  - Allows all review/inspection activities to align
  - First done internally to check out system, now roll out externally
- Base TADs on workload management factors
  - Exception: For big first generics, assign TADs to roughly correspond with expiry/earliest possible date FDA could approve ANDA

Target Action Dates (TAD) "A Work in Progress"

Start notifying applicants

- Communication tool being finalized
- Not all TADs will be assigned all at once
- In 1st QTR CY2015, ~1,000 assigned
  - Commitment to notify industry by end of March 2015
- TADs will be March to September 2015
- Again, for big first generics, will receive TADs to roughly correspond with patent expiry/earliest possible date FDA could approve ANDA
- "Peel the onion" – layer by layer approach

TADs IMPLEMENTATION

- NO Guidance or MAPP
- One TAD per ANDA; TADs are fixed
- Cannot exchange one ANDA TAD for another
    - Workload factors are used to assign TAD and predict potential approval
- We may miss a TAD if we can get an ANDA to approval in a short amount of time
    - Easy information exchange with applicant
    - Reduces number of review cycles

"Communications" Next Steps

- Iterative, "real-time communications" (RTC) re: deficiencies in current review cycle
- Update "Communications with Industry MAPP" to formalize and clarify changes
- "Launch planning updates" for big first generics "x" and "y" months before TAD
  - Would be akin to a "Pre-Action Notification"
  - Communication "how to" still being worked on
  - Again, work in progress

COMMUNICATION & PARTNERSHIP

- FDA - GPhA Board of Directors Quarterly meetings

http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm370616.htm

- Frequent conversations
- Lots of interaction, feedback
- Weekly t-cons, if not more frequently

FORMULA FOR SUCCESS

A Rosy Future

1. Increased review capacity---more throughput
2. 1st generics prioritized
3. Review and inspections coordinated
4. More Communication
5. Approvals
6. While meeting all Year 3, 4, & 5 Goals

PROMISE OF GENERIC DRUGS

- Improve Public Health by ensuring access to more affordable medicines
- Assure high quality generic medicines
- Maintain public trust and confidence by payers, providers and patients

FDA & CDER take pride in its strong track record of fulfilling user fee commitments


OFFICE OF GENERIC DRUGS
OGD
Affordable, Quality Medicines
1984

THANK YOU!